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Cardiovascular Bioinstrumentation

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ON CARDIOVASCULAR BIOINSTRUMENTATION (NASA)
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Cardiovascular Bioinstrumentation

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A. BACKGROUND

1. ARC History in Cardiovascular (CV) Instrumentation Development

The Ames Research Center (ARC) has a long history in the development of CV instrumentation for human and animal research. The ARC Cardiovascular Research Lab under the Space Physiology Branch, Space Research Directorate, supports both ground-based and space-based animal and human research goals. The Cardiovascular Research Laboratory was established at ARC in the mid-1960's to conduct ground-based animal research and support development of advanced cardiovascular instrumentation applicable to spaceflight. The ARC Biomedical Research Program also conducts human studies with a CV instrumentation focus.

Specific instrumentation developed at ARC has included items ranging from long-duration, flexible, dry EKG electrodes for animal or human use to an inductively-powered, implantable, multi-channel telemetry system for Rhesus monkeys which measures the EKG, mean aortic pressure, mean left ventricular pressure, and intrathoracic temperature. A carotid blood flow and pressure cuff developed for Rhesus monkeys flew on Cosmos biosatellite missions 1514, 1667 and is proposed for a 1989 Cosmos mission in modified form.

2. Need for Review/Coordination of Future CV Instrumentation Development

Based on the ARC expertise in CV instrumentation development and the high science priority of cardiovascular research in the support of man-in-space for extended durations, the Life Sciences Projects Office (LSPO) held a conference to review the status of current and proposed R & D efforts both within and outside of NASA. A recent JSC-sponsored Workshop was also held for this purpose which focused on human, on-invasive CV instrumentation for Space Station. A list of proposed LSPO experiment payloads with a cardiovascular focus, current estimated flight dates and associated animal specimens is shown in Table 1.

To evaluate the status of CV instrumentation development, the Conference was conducted at ARC on July 21-22, 1987 to which NASA Primary Investigators and their engineering support personnel, representatives of the bioinstrumentation development and manufacturing community and NASA science and engineering management were invited. A list of the 42 attendees is included in Attachment 1. A similar evaluation was conducted for ARC by a NASA contractor about 10 years ago.

TABLE 1
CARDIOVASCULAR FLIGHT EXPERIMENTS

Mission	Date	PI/Advisor	Species
Cosmos '89	1989	Vatner	Rhesus monkey
SLS-1	1990	Hutchins Popovic	Rat Rat
SLS-2	1992	Hutchins Popovic Moore-Ede	Rat Rat Squirrel monkey
IML-2	1992	Vatner Moore-Ede	Rhesus monkey Rhesus monkey
SLS-3	1993	Moore-Ede	Squirrel monkey

B. CV BIOINSTRUMENTATION CONFERENCE GOALS

The two major goals for the ARC CV Bioinstrumentation Conference are listed below with corresponding sub-goals.

1. Review Science Requirements/Instrumentation Capabilities

- Review proposed cardiovascular science requirements
- Assess science requirement commonality across species
- Review current instrumentation capabilities
- Assess instrumentation R & D required for accurate, precise measurements of cardiovascular parameters in the space craft

2. Assess Instrumentation Development Methods/Coordination Options

- Assess modes for increased scientist/technologist interaction
- Review options for joint NASA/Industry R & D cooperation
- Assess ARC CV Bioinstrumentation Conference as model for improving R & D coordination

C. REQUIREMENTS/CAPABILITIES SUMMARY

1. Cardiovascular Science Requirements

Presentations were given by NASA-sponsored Primary Investigators and/or Science Advisors to define science requirements for their animal specimens of choice. These are briefly listed below and are summarized by measurement parameter and specimen type in Table 2.

- R. Ballard – NASA Ames Research Center, Moffett Field, CA

Introduction

- S. Vatner – Harvard Medical School, Southboro, MA

Blood pressure

Blood flow

Cardiac dimensions

Specimen: Rhesus monkey

- S. Churchill (M. Moore-Ede) – Harvard Medical School, Boston, MA

Blood pressure

Heart rate

Chronic catheters for blood sampling, fluid volumes

Specimen: Rhesus monkey/squirrel monkey

- P. Hutchins – Bowman Gray School of Medicine, Winston-Salem, NC

Blood pressure

Blood flow

Microvascular dimensions/morphology

Fluid volumes

Specimen: Rat

- V. Popovic – Emory University, Atlanta, GA

Vascular catheters for blood sampling

Blood flow

Specimen: Rat

- J. Buckey - University of Texas, Dallas, TX

Baroreflex test
Cardiac output
Central venous pressure
Specimen: Human

Viewgraphs and/or handouts available from the science presentations are included as Attachment 3.

2. Instrumentation Capabilities

Presentations were given by bioinstrumentation industry representatives on their cardiovascular sensor systems potentially applicable to use in spaceflight. These are briefly listed below and are summarized in Table 3 into five measurement types with technology options. Viewgraphs and/or handouts from the industry presentations are included in Attachment 4.

- H. Finger - NASA Ames Research Center, Moffett Field, CA

Introduction

- R. Eberhart - Johns Hopkins Univ., Laurel, MD

Biomedical implantable devices for fluid sampling
Medication/materials compatibility studies
Multichannel implantable telemetry system (temperature, EKG, blood pressures, flow) - PATS
Non-thrombogenic, biocompatible catheter materials
Microelectronics lab for development (future)

- C. Drost - Transonic Systems, Inc., Ithaca, NY

Transit-time implantable blood flowmeter (volume flow)

- B. Brockway - Data Sciences, Roseville, MN

Small animal implantable telemetry (piezo-resistive blood pressure sensor via fluid-filled catheter, EKG, heart rate)

TABLE 2

CARDIOVASCULAR/FLUID-ELECTROLYTE MEASUREMENTS

MEASUREMENT	RHESUS MONKEY	SQUIRREL MONKEY	RAT	HUMAN
Pressure:				
Aorta	X	X	X	
Mean Arterial (Non-invasive)				X
Left Ventricular	X		X	
Right Atrial (CVP)	X	X	X	X
Flow:				
Ascending Aorta (CO)	X		X	X
Regional Blood				
Renal		X	X	
Mesenteric			X	
Illiatic			X	
Brain			X	
Heart			X	
Carotid				X
Femoral				X
Microcirculation			X	
Left Ventricular Size	X		X	Y
EKG	X	X	X	X
Urine	X	X	X	X
Fluid Compartments:				
ECF	X	X		X
PV	X	X		X
TBW	X	X		X
BV (by location)			X	
Regional Compliance:				
venous	X		X	X
peripheral				
central				
tissue				X
Blood:				
Serum	X	X	X	X
Gasses, pH	X		X	
Ions (Na ⁺ , K ⁺ , Ca ⁺⁺)	X (In vitro)	X (In vitro)		

CVP = Central Venous Pressure; CO = Cardiac Output; ECF = Extracellular Fluid; PV = Plasma Volume; TBW = Total Body Water; BV = Blood Volume

- E. Luzzi - L & M Electronics, Daly City, CA

Automated blood flow/pressure system for spaceflight
(external to vessel, hardware implant)

- C. Parker - Millar Instruments, Houston, TX

Catheter-tip implantable blood pressure/doppler flow
systems for animal/human use (existing device is acute
implant, but chronic implant is planned)

TABLE 3
TRANSDUCER CANDIDATES

PRESSURE

- Indwelling pressure sensor
- External sensor with fluid filled catheter
- Piezoresistive
- Capacitative
- Laser
- Fiber optic
- Magnetoresistive

FLOW

- Doppler - pulse
- Doppler - CW (continuous wave)
- Doppler - Optical laser
- Electromagnetic Flowmeter
- Transit-time
- Thermal Dilution
- Ultrasonic
- Microsphere

CARDIAC DIMENSION

- Ultrasonic crystals (instantaneous cardiac dimensions)
- Piezoelectric film devices
- Imaging ultrasound
- Fast computed tomography (CT)
- Magnetic nuclear resonance (MRI)

MICROCIRCULATION

- Implantable video sensors

EKG

- Telemetry
 - Hardwired (cutaneous/subcutaneous implant)
 - 2 vs. 3 lead

D. SPLINTER GROUP MEETINGS

Splinter group meetings were held on the development of science requirements and priorities (SCIENCE SPLINTER GROUP) and instrumentation development methods/coordination options (HARDWARE SPLINTER GROUP).

1. Science Splinter Group

The summary results from the review of science requirements and related issues/concerns are grouped by measurement type, below.

PRESSURE

A. SCIENCE REQUIREMENTS (1) - ARTERIAL PRESSURE

SPECIES: Rhesus monkey/squirrel monkey, rat

MEASUREMENT LOCATION: Aorta, Left Ventricle

ATTACHMENT TECHNIQUE: Intravascular, with non-fluid filled lines

SIZE: TBD, 1 mm or less in diameter for rats

SENSOR STABILITY: need 1-2 mm Hg/month, predictable linear zero drift

B. SCIENCE REQUIREMENTS (2) - VENOUS PRESSURE

SPECIES: Rhesus monkey/squirrel monkey, rat

MEASUREMENT LOCATION: Central venous location (right atrium)

ATTACHMENT TECHNIQUE: Intravascular, with fluid-filled lines desired initially, as blood sample is typically desired; later, solid-state non-fluid filled lines will be preferable.

SIZE: TBD

SENSOR STABILITY: 0.5-1.0 mm Hg/month, predictable linear zero drift

C. ISSUES/CONCERNS

Stable baseline/predictable drift

Fibrotic coating at blood interface

Sensitivity and resolution

Automatic compensation for: (with same accuracy and stability as sensor)

thoracic pressure

ambient pressure changes

Sizing for animals down to the size of adult rodents

Telemetered applications desirable with little or no acute catheterization needs

Blood sampling method

Maintain bioisolation

FLOW

A. SCIENCE REQUIREMENTS (1) - AORTIC (CARDIAC OUTPUT)

Species: Rhesus monkey, rat

MEASUREMENT LOCATION: Aorta

ATTACHMENT TECHNIQUE: Extravascular

SIZE: TBD, vessel diameter as small as 2 mm

SENSOR STABILITY: TBD, ideally ± 2 ml/min per month

B. SCIENCE REQUIREMENTS (2) - REGIONAL (Renal, Mesenteric, Iliac)

SPECIES: Rhesus monkey, squirrel monkey, rat

MEASUREMENT LOCATION: Renal, Mesenteric, Iliac Arteries

ATTACHMENT TECHNIQUE: Extravascular

SIZE: TBD, 1 mm or less in diameter for rats

SENSOR STABILITY: Accurate zero required, stability is TBD

C. ISSUES/CONCERNS

Vessel deformation and/or restriction

Most advantageous technology, not chronically implantable

Sensitivity to turbulence/flow velocity profile

Reduced power consumption

Size constraints

Electromagnetic compatibility

Compatibility with pressure and dimension measurements

Positioning errors/site stability

Site availability

D. SCIENCE REQUIREMENTS (3) - REGIONAL (Brain, Heart)

SPECIES: Rhesus monkey, squirrel monkey, rat

MEASUREMENT LOCATION: Brain, Coronary Arteries

ATTACHMENT TECHNIQUE: Microsphere injection, Imaging (MRI, PET, CT)

SIZE: TBD

SENSOR STABILITY: TBD, accommodate calibration

E. ISSUES/CONCERNS

Radioactivity/Isotopes

Catheterization

Animal sacrifice

CARDIAC DIMENSION

A. SCIENCE REQUIREMENTS – LEFT VENTRICULAR DIMENSION

SPECIES: Rhesus monkey, squirrel monkey, rat, human

MEASUREMENT LOCATION: Left Ventricle

ATTACHMENT TECHNIQUE: Direct implant of ultrasonic crystals; Non-invasive
Echocardiogram or fast CT

SIZE: TBD

SENSOR STABILITY: TBD, ideally ± 0.01 mm/month

B. ISSUES/CONCERNS

Compatibility with flow measurements

Instantaneous and continuous

Reduced power consumption and size for telemetry

Need Left ventricular and End diastolic pressure simultaneously

MICROCIRCULATION

A. SCIENCE REQUIREMENTS – MICROCIRCULATION MORPHOLOGY

SPECIES: Rhesus monkey, squirrel monkey, rat

MEASUREMENT LOCATION: Subcutaneously

ATTACHMENT TECHNIQUE: TBD, currently videomonitor but ideally direct video
implant

SIZE: 10 mm dia. x 2 mm thick

SENSOR STABILITY: Ideally ± 0.001 mm/month

B. ISSUES/CONCERNS

Data rate

Size

Power Consumption

EKG

A. SCIENCE REQUIREMENTS – ELECTROCARDIOGRAM

SPECIES: Rhesus monkey, squirrel monkey, rat

MEASUREMENT LOCATION: Subcutaneously

ATTACHMENT TECHNIQUE: Subcutaneous

SIZE: Three lead Biopotential

SENSOR STABILITY: N/A

B. ISSUES/CONCERNS

Data rate (wave form vs. event)

COMMON ISSUES/CONCERNS

Schedule
Power
Size
Sensitivity and Resolution
Drift/Stability
Calibration frequency/procedures
Measurement resolution accuracy
Implant duration (9 - 18 months)
 technical issues
 biocompatibility issues
Free-ranging vs. restrained subjects
Bioisolation (fluid-filled catheter vs. electrical lines, etc.)
Failure Mode Effects Analysis
Crew safety
Automation vs. crew time
Data rate

2. Hardware Splinter Group

A CV Sensor/Transducer Assessment form was filled out for each transducer candidate identified by the Workshop participants which was judged applicable to one of the five cardiovascular measurement types reviewed. For each sensor/transducer type, the form included an assessment of Measurement Site/Vessel; Attachment/Implant Method; Development Status (near-term, long-term); Advantages/Disadvantages and Recommendations. These assessments are included as Attachment 2. Two highly-applicable CV instrumentation assessment reports prepared recently for ARC were obtained after the Workshop and utilized as additional sources for preparation of the assessments. A brief description of each of the sensor/transducer technologies is given below.

CV SENSOR/TRANSDUCER TECHNOLOGY DESCRIPTIONS

PRESSURE

1. Piezo-resistive semiconductor

Commonly used transducer which consists of a diaphragm with attached semiconductor strain gauges. Requires a micropower amplifier and is often used with other sensors in a multi-channel application. The low milliwatt bridge excitation voltage can be duty-cycled to conserve power while providing continuous data output. Konigsberg Instruments, Inc. makes a titanium diaphragm with stainless steel leads in sizes from 3.5 to 7.0 mm dia. available as combination pressure transducer/EKG electrodes.

Transducers have standard calibration range of 0 to +300 mm Hg and 0 to +100 mm Hg. Typical drift is 3-20 mm Hg/month for smaller and 1-6 mm Hg/month for larger transducers.

2. Pressure-sensitive capacitor

A variation on 1, above, where a pressure-sensitive capacitor is used. Stanford Univ. has worked on an implantable, micropowered IC for this type of sensor.

3. Fiber optic LED

Camino Labs in San Diego has a commercial product using this technique. The sensor is sealed and built into the tip of an intravascular catheter (as small as #4 French). Light is transmitted down an optical fiber to a gold-plated sealed metal bellows which has a reflective surface facing the interior of the catheter. The bellows is exposed to the blood (or other fluid) on the outside of the catheter and senses the pressure changes which produce movement of the reflective surface. A receiving optical fiber transmits reflected light down the catheter to an external photo diode/LED device which converts light energy to electrical energy. Has been used in humans and animals as small as large rats. Pressure range is -10 to 200 mm Hg, drift is quite stable after 24-48 hours (3 mm Hg) and is only moderately temperature sensitive (2-3 mm Hg shift from 70 -105° F).

4. Fiber optic laser - TBD

A similar technique to fiberoptic LED except based on laser technology. No commercial product yet developed.

5. Magneto-resistive - TBD

FLOW

1. Electromagnetic

Utilizes principle that an electromotive force is produced when a conductor moves in a magnetic field. Typically the magnetic coil is placed in a cuff around the vessel to be monitored as are two sensing electrodes which must be in electrical contact with the vessel. The electrodes sense an EMF which is proportional to flow velocity. They are made with either AC field coils or permanent magnets. Probes come in wide variety of sizes since they do require a snug fit to the vessel. The AC field coil requires a four

conductor cable with shielding which can be relatively stiff. The DC permanent magnet requires no power and only two cable leads but has less baseline stability. Interference with other electrical signals (i.e., EKG) in same area is possible.

2. Ultrasound, transit-time

Utilizes alternating pulse-catch ultrasonic technology to measure the difference between the time it takes a sound wave to travel a fixed reflective pathway through a moving fluid in the direction of the flow and the time necessary for the beam to travel the same pathway in the opposite direction (against the flow). Transit-time varies with the average flow velocity encountered by the ultrasound. The use of wide-beam transducer crystals creates an ultrasonic beam which includes the entire cross-sectional area of the flow in a way analogous to integrating a narrow beam over the width of the vessel. Hence volume flow, not velocity, is measured directly in a manner independent of both velocity flow profile and vessel cross-sectional area. The reflective pathway crosses the flow twice to yield a measure of flow essentially independent of vessel-probe alignment and flow turbulence. Good zero stability. Uses relatively loose-fitting, non-constrictive probe which requires only acoustic contact with the vessel. Allows for long-term implantability with vessel growth and pulsatile diameter changes. Requires 4-strand microfine (1 mm total o.d., including insulation and jacket) flexible cable.

3. Pulse doppler

Similar to 4, below, but utilizes only one crystal. Provides flow velocity only. Less acoustical and electrical interference with other sensors than CW doppler. Has a high velocity limitation (such as rat aortic flow). Both methods have good frequency response.

4. Continuous wave (CW) doppler

Utilizes bi-directional doppler technique (two crystals) to sense frequency shift due to moving blood. Provides flow velocity only and probe must be snug fit. Good baseline stability and has a definite zero flow capability. Relatively lightweight and flexible probes.

5. Optical laser doppler - TBD

6. Thermal dilution, microsphere injections - TBD

7. Microspheres - TBD

CARDIAC DIMENSIONS

1. Ultrasonic crystals - TBD
2. Piezoelectric film - TBD
3. Imaging ultrasound, fast computer tomography (CT), magnetic nuclear resonance (MRI) - TBD

MICROCIRCULATION

1. Video sensor - TBD
2. Laser doppler - TBD

EKG

1. 2 lead

Well-developed sensor technologies which typically use highly-flexible leads made by coiling stainless steel wires in silastic tubing. Require only micropower amplifiers and are often used with other sensors in multi-channel applications. Heart rate is typically derived from EKG usually at the receiver. Two-lead systems will give an approximation of the EKG wave useful for calculating heart rate.

2. 3 lead

The same technology as 1, above, but the third lead acts as an inactive electrode thus providing an EKG wave which can reflect cardiac conduction events.

E. RECOMMENDATIONS

1. Science Splinter Group Recommendations

What type of program should be developed for technology development/biocompatibility testing?

New technology development should be driven by peer-reviewed scientific objectives and requirements. Such hardware should be tested and approved by the Investigators using the technology and accepted as valid by their science peers.

Should NASA establish a continued interaction between the scientific and commercial communities? If so, how?

Yes, continued communication between the scientific and commercial communities is critical.

Throughout the NASA design/development process (Phases A-D), all interested parties (NASA, Investigators, crew and manufacturers) must continually interact to produce the most effective end product. This process must include prototype production and the final product must be capable of being upgraded as the technology evolves. Sufficient numbers of the prototypes and final products must be manufactured for Investigator use, crew training, ground testing, control studies and flight.

2. Hardware Splinter Group Recommendations

This Group strongly endorsed the recommendations above from the Science Splinter Group. In addition, they addressed the questions below.

How useful is the workshop format for identifying instrumentation requirements and potential teams for hardware development?

It is critical that scientist/technologist interaction on the issue of bioinstrumentation development for spaceflight occur within the context of NASA's flight program constraints in order to maximize early development of usable systems. NASA should consider the option of identifying science and technology advisors for specific areas of bioinstrumentation who have significant knowledge of NASA's programmatic issues in addition to specific technical knowledge. These advisors could provide planning support for both NASA and industry by ensuring that science and hardware requirements are clearly defined and NASA programmatic issues such as performance specifications, budget and schedule are known.

The workshop format seems ideal for identifying top-level requirements, identifying areas of expertise, and potential teams for supporting and conducting hardware development. Some technical experts identified but not in attendance at a given workshop, should be contacted after so they can be included in the developing network.

What is the relation between special-purpose NASA flight bioinstrumentation and larger market commercial versions?

A strong recommendation was made for ensuring maximum linkage between the development of NASA spaceflight instrumentation and commercial instrumentation to allow future upgrades of NASA technology as they are developed for commercial markets. The concept of flight qualifying commercial hardware was recommended as one method to ensure this linkage. This concept consists of modifying commercial hardware/software to meet flight requirements to the maximum degree possible. This process will require close coordination between NASA and industry.

What options exist for NASA/industry research and development cooperation?

New mechanisms available for NASA support of industry bioinstrumentation R & D for spaceflight were identified such as SBIR grants. Industry representatives recommended that NASA encourage informal industry proposals suitable for preliminary review and provision of an industry support system if more elaborate proposals are required to meet complex government contracting requirements. New NASA/industry joint venture agreements available through the NASA Commercial Programs Office were considered viable options for cooperative development. Assuming strong interest by both parties, industry would be amenable to providing their resources in a cost-sharing manner with NASA.

3. Additional Recommendations

What is the relation between bioinstrumentation development for human and animal subjects?

Based on the list of cardiovascular-related science measurements proposed for spaceflight listed in Table 2 above, it is apparent that there is strong interest in utilizing subjects ranging from rodents to humans for a given measurement. This requirement has a long history in the biological sciences and not surprisingly continues as a viable concept in the

spaceflight era. The challenge for spaceflight bioinstrumentation developers is to provide maximum utilization of common and even commercial equipment along with specimen-unique sensor development in order to ensure high flexibility in applications with the lowest development cost.

What cardiovascular sensors appear to be good options for near-term development based on the science return on investment?

Additional analysis of the technologies identified will be required to make comprehensive recommendations in this area. In general, however, blood pressure and blood flow sensors appear to be near-term technology candidates which could benefit strongly from NASA-sponsored development. Another area which appears to be a likely candidate for near-term development is pre/postflight cardiac dimensions measured by non-invasive imaging methods.

What constitutes a cardiovascular sensor?

The need for developing not just sensors but "sensor systems" was recommended for implantable cardiovascular instrumentation. These "systems" would include at a minimum transducers, fixtures, packaging, leads, connectors and feedthroughs. Improvements in the design and integration of these elements can be as important as breakthroughs in transducer development.

F. ATTACHMENTS

1. Attachment 1 - Agenda and Attendee List
2. Attachment 2 - Cardiovascular Sensor/Transducer Assessments
3. Attachment 3 - Science Viewgraphs/Handouts
4. Attachment 4 - Industry Viewgraphs/Handouts

ATTACHMENT 1
AGENDA
&
LIST OF ATTENDEES

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AGENDA

CARDIOVASCULAR BIOINSTRUMENTATION MEETING NASA-AMES RESEARCH CENTER JULY 21-22, 1987

TUESDAY, JULY 21

0830 Opening Remarks
0900 Presentations by Scientists

R. Ballard, ARC
S. Vatner, Harvard
S. Churchill, Harvard
P. Hutchins, Bowman-Gray
V. Popovic, Emory
J. Buckey, Univ. of Texas

1030 Break
1045 Presentations by Bioinstrumentation-
Engineering Representatives

H. Finger, ARC
Russell Eberhart, JHU
Cor Drost, Transonics Corp
David Osgood, Mini-Mitter
Ed Luzzi, L&M Electronics
C. Parker, Millar Inst. Inc.

1200 Lunch
1300 Bioinstr-Engineering Presentations cont'd.
1400 Open Discussion

WEDNESDAY, JULY 22

0830 Splinter Groups: Science Interests
Hardware Interests
1300 Reports from splinter groups
1430 Summary and Recommendations

C. Fuller/R. Ballard
R. Mains/H. Finger

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ATTACHMENT 2

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORMS

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Blood Pressure

SENSOR/TRANSDUCER TYPE: Piezo-resistive semiconductor

MEASUREMENT SITE/VESSEL: Arteries/veins of TBD size

ATTACHMENT/IMPLANT METHOD: Direct intravascular or external via intravascular fluid-filled catheter, extravascular aplanation

DEVELOPMENT STATUS:

1. Near-term

- available technology, chronically implantable inside vessels of 7 mm dia. and larger
- drift of 1-2 mm Hg/month (best case)
- about 2.5 mm dia. minimum with acceptable drift
- signal conditioning developed, telemetry already developed
- extravascular aplanation method used with Rhesus monkeys in Cosmos Biosatellite Project for 60-90 day duration
- fluid-filled intravascular catheters (arterial/venous) with external transducers proposed for Squirrel monkeys on SLS-1 flight

2. Long-term

- may eventually yield to more stable measurement methods
- with partial duty cycle could be good candidate for totally implanted telemetry systems using power vests to allow free-ranging subjects

ADVANTAGES/DISADVANTAGES:

- applicability to rodents difficult because of small vessels
- good candidate for next 5 years
- requires sensor selection after testing to get highest performance
- fabrication methods (packaging) need improvement
- automotive industry has commercial interest
- typically requires restrained subjects for continuous monitoring due to signal conditioning

RECOMMENDATIONS

- assess large industry interest and involvement to improve packaging and interchangeability
- well-established technology can likely be improved

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Blood pressure

SENSOR/TRANSDUCER TYPE: Fiber optic LED

MEASUREMENT SITE/VESSEL: Arteries/veins as small as 1 mm dia.

ATTACHMENT/IMPLANT METHOD: Direct intravascular

DEVELOPMENT STATUS:

1. Near-term

- commercially available from Carino Labs, San Diego
- current drift is moderate after first 48 hours
- used for only 72 hours chronically exposed to blood due to clotting, 5-7 days for cerebral spinal fluid

2. Long-term

- long-duration chronic application is TBD

ADVANTAGES/DISADVANTAGES:

- good potential for low drift
- signal processing requirements moderate
- suitability for chronic application is TBD

RECOMMENDATIONS:

- technology simple and reliable
- need evaluation for use in chronic application

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Blood pressure

SENSOR/TRANSDUCER TYPE: Pressure-sensitive capacitor

MEASUREMENT SITE/VESSEL: Arteries/veins as small as 1 mm dia.

ATTACHMENT/IMPLANT METHOD: Direct intravascular or external via intravascular fluid-filled catheter, extravascular aplanation

DEVELOPMENT STATUS:

1. Near-term

- Konigsberg tested 7 mm dia. intracranial unit in past with 1 mm Hg/month drift
- Stanford University (Smith/Meindl) working on implantable, micro-powered IC with pressure-sensitive capacitor
- Pacesetter, Inc. and Case Western Univ. may have done some R & D

2. Long-term

- potential for low-power, low-drift, simple fabrication
- signal conditioning relatively complex

ADVANTAGES/DISADVANTAGES:

- could be as small as 1 mm dia.
- low drift potential good
- packaged into a single IC for telemetry

RECOMMENDATIONS:

- good candidate for near-term development (within 5 years)
- review current development efforts (see above)
- good return potential for early investment in R & D.

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Blood pressure

SENSOR/TRANSDUCER TYPE: Fiber optic laser

MEASUREMENT SITE/VESSEL: Arteries/veins as small as 1 mm dia.

ATTACHMENT/IMPLANT METHOD: Direct intravascular, others TBD

DEVELOPMENT STATUS:

1. Near-term

- beyond current state-of-art
- current drift is about 3 mm Hg/day
- high power consumption would require duty-cycling

2. Long-term

- telemetry application would require much work due to high power consumption

ADVANTAGES/DISADVANTAGES:

- good potential for low drift
- signal processing requirements average
- high power consumption and drift requires R & D

RECOMMENDATIONS:

- good candidate for long-term development only

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Blood pressure

SENSOR/TRANSDUCER TYPE: Magneto-resistive

MEASUREMENT SITE/VESSEL:

ATTACHMENT/IMPLANT METHOD:

DEVELOPMENT STATUS:

1. Near-term

- Honeywell has done some R & D and unit available

2. Long-term

- TBD

ADVANTAGES/DISADVANTAGES:

- requires low power

RECOMMENDATIONS:

- possibility for early development, needs evaluation

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Blood flow

SENSOR/TRANSDUCER TYPE: Electromagnetic

MEASUREMENT SITE/VESSEL: Arteries and veins as small as 2.5 mm dia.

ATTACHMENT/IMPLANT METHOD: In contact with vessel wall exterior

DEVELOPMENT STATUS:

1. Near-term

- System being developed/tested for SLS-1 rodent PI at ARC using hardwire connection via tether
- Honeywell has system which assumes zero in late diastole
- high drift, high power consumption problems
- thickens arterial wall from current fields

2. Long-term

ADVANTAGES/DISADVANTAGES:

- high drift, high power consumption
- not useful in small vessels due to high zero offset drift
- biocompatibility concerns
- affects other electrical measurements (ECG, etc.)

RECOMMENDATIONS:

- monitor evaluation underway at ARC for SLS-1 rodents
- not recommended for long-term development

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Blood flow

SENSOR/TRANSDUCER TYPE: Ultrasound, transit-time

MEASUREMENT SITE/VESSEL: Arteries and veins of various sizes

ATTACHMENT/IMPLANT METHOD: Adjacent to vessel, only loose acoustic coupling required

DEVELOPMENT STATUS:

1. Near-term

- available from Transonic Systems, Inc.
- SBIR grant from NIH to develop model for use in 2.5 mm dia. and lower range
- telemetry capability within 3-5 years, Westbrook concept developed for ARC during FY '87

2. Long-term

- improvements in packaging, telemetry addition likely
- VLSI, CMOS and signal conditioning R & D required

ADVANTAGES/DISADVANTAGES:

- uses pulsed, low-power technique for volume-flow
- currently requires hardwire connection between sensor and power
- good long-term implant potential
- non-constrictive application, insensitive to angle
- strong industrial and medical interest should support R & D

RECOMMENDATIONS:

- excellent candidate for near-term development
- monitor improvements already underway by vendor

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Blood flow

SENSOR/TRANSDUCER TYPE: Pulse doppler

MEASUREMENT SITE/VESSEL: Arteries and veins of various sizes

ATTACHMENT/IMPLANT METHOD: Crystals held in cuff around vessel

DEVELOPMENT STATUS:

1. Near-term

- available, much baseline data, chronically implantable
- Stanford Univ. (Yeung) developing totally implantable system for multichannel telemetry, report available soon
- Baylor College of Medicine (Hartley) developing technique for measuring cardiac output in rats using subcutaneous induction coil for power/signal conditioning
- work underway on lessening power requirement
- small probes use single crystal
- leads need improvement
- pulsed doppler + B-scan provides flow velocity plus dynamic tracking of vessel diameter for volume flow estimates

2. Long-term

- need to reduce cuff size and data transmission bandwidth requirements for telemetry
- takes less power than similar CW doppler method

ADVANTAGES/DISADVANTAGES:

- cuffs are constrictive of vessel
- improvements are likely in miniaturizing and power requirements
- requires complex signal conditioning with relatively high power
- flow velocity only, volume flow requires direct imaging of vessel walls with precise positioning.
- requires occlusive zero flow calibration
- system is totally implantable

RECOMMENDATIONS:

- development focus is vague, needs review
- assess B-scan option
- may be superior to CW doppler because of less power, more information contained in data (especially gated version)

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Blood flow

SENSOR/TRANSDUCER TYPE: Continuous wave (CW) doppler

MEASUREMENT SITE/VESSEL: See pulse doppler

ATTACHMENT/IMPLANT METHOD: See pulse doppler

DEVELOPMENT STATUS:

1. Near-term - See pulse doppler
 - Stanford Univ. has telemetry version
 - single crystal available
2. Long-term - See pulse doppler

ADVANTAGES/DISADVANTAGES:

- has flown in space (Cosmos 1514, 1667 biosatellites)
- signal conditioning more complex than pulse doppler
- applicable to very small vessels
- flow velocity only, volume flow requires vessel thickness estimates so accuracy compromised

RECOMMENDATIONS:

- near term development candidate but pulse doppler is similar and may be preferable (see above)

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Blood flow

SENSOR/TRANSDUCER TYPE: Optical laser doppler

MEASUREMENT SITE/VESSEL: See pulse doppler

ATTACHMENT/IMPLANT METHOD: See pulse doppler

DEVELOPMENT STATUS:

1. Near-term

- currently beyond state-of-art

2. Long-term

- could embed fibers into organ tissue to get regional perfusion data
- much development required

ADVANTAGES/DISADVANTAGES: TBD

RECOMMENDATIONS:

- not a good candidate for early development.

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Blood flow

SENSOR/TRANSDUCER TYPE: Thermal dilution, microsphere

MEASUREMENT SITE/VESSEL: See recommendations below

ATTACHMENT/IMPLANT METHOD: See recommendations below

DEVELOPMENT STATUS: See recommendations below

1. Near-term

- Nejad and Ogden reported a technique for rodents in a NASA publication 15 years ago.

2. Long-term

- Minimal change anticipated

ADVANTAGES/DISADVANTAGES: See recommendations below

RECOMMENDATIONS:

- Both techniques currently not applicable to spaceflight constraints due to one or more of the following: substantial requirements for specimen restraint, anesthesia, vascular injection, one-time measurement, specimen sacrifice, and/or complex sensor development.

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Cardiac dimensions

SENSOR/TRANSDUCER TYPE: Ultrasonic crystals

MEASUREMENT SITE/VESSEL: Surface of heart

ATTACHMENT/IMPLANT METHOD: Sutured to surface of heart

DEVELOPMENT STATUS:

1. Near-term

- available technology, but chronic implant needs development
- transit-time dimension gauges (sonomicrometers) and gated doppler probes have been used

2. Long-term

- needs much development for simplifying circuitry and biocompatibility for long-term implants

ADVANTAGES/DISADVANTAGES:

- well-developed technology
- complex circuitry required
- currently needs to be hardwired
- may interfere with flow sensors of same type if in same location if operational cycling not possible

RECOMMENDATIONS:

- testing required for assessing long-term implant biocompatibility and capabilities for total implantation of sensors
- evaluate power requirements

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Cardiac dimensions

SENSOR/TRANSDUCER TYPE: Piezoelectric film

MEASUREMENT SITE/VESSEL: Surface of heart

ATTACHMENT/IMPLANT METHOD: Sutured to surface of heart

DEVELOPMENT STATUS: See recommendations below

1. Near-term

2. Long-term

ADVANTAGES/DISADVANTAGES: See recommendations below

RECOMMENDATIONS: Very early conceptual stage, applicability to cardiac dimensions measurement is TBD.

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Cardiac dimensions

SENSOR/TRANSDUCER TYPE: Imaging ultrasound, Fast CT, MRI

MEASUREMENT SITE/VESSEL: Cardiac chambers

ATTACHMENT/IMPLANT METHOD: External sensors placed adjacent to thorax at various distances

DEVELOPMENT STATUS:

1. Near-term

- well-developed technologies for human studies and used with larger animal specimens
- require highly-restrained or tranquilized animal specimens
- applicable to pre/postflight studies when subjects can be easily handled and/or tranquilized

2. Long-term

- will require dramatic advance in miniaturization of systems and less constraints on movement of specimen to be useful in space flight

ADVANTAGES/DISADVANTAGES:

- good cross-over to human studies
- technologies currently not applicable to inflight animal studies
- MRI may be incompatible with metallic implants in specimens
- may interfere with flow sensors

RECOMMENDATIONS:

- consider for pre/postflight studies now
- major technology advances required for consideration as inflight systems.

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Microcirculation of tissues

SENSOR/TRANSDUCER TYPE: Video sensor, laser doppler

MEASUREMENT SITE/VESSEL: Vascular beds

ATTACHMENT/IMPLANT METHOD: Implanted in tissue adjacent to vascular bed or just external to vascular "window" created by a chronic muscle flap surgical procedure

DEVELOPMENT STATUS: See recommendations below

1. Near-term

Pixel arrays currently available for video. Commercial laser doppler instruments used in humans

2. Long-term

High-resolution devices under development

ADVANTAGES/DISADVANTAGES: See recommendations below

RECOMMENDATIONS: Video technologies are beyond state-of-the-art and good candidates only for long-term development. The Japanese have reported interest in developing implantable video sensors, however. Commercial laser doppler instruments should be evaluated.

CARDIOVASCULAR SENSOR/TRANSDUCER ASSESSMENT FORM

MEASUREMENT: Electrocardiogram (EKG)

SENSOR/TRANSDUCER TYPE: 2 or 3-lead sensors

MEASUREMENT SITE/VESSEL: Intra or extra-thoracic but subcutaneous

ATTACHMENT/IMPLANT METHOD: Surgically implanted in appropriate site for 2 or 3 lead (one ground) sensors

DEVELOPMENT STATUS:

1. Near-term

- recent spaceflight telemetry experience by US and Soviets in rodents, squirrel monkeys and Rhesus monkeys
- proven technology
- longevity of leads needs improvement

2. Long-term

- improvements likely in pre-processing of data
- flexible wire electrodes status TBD

ADVANTAGES/DISADVANTAGES:

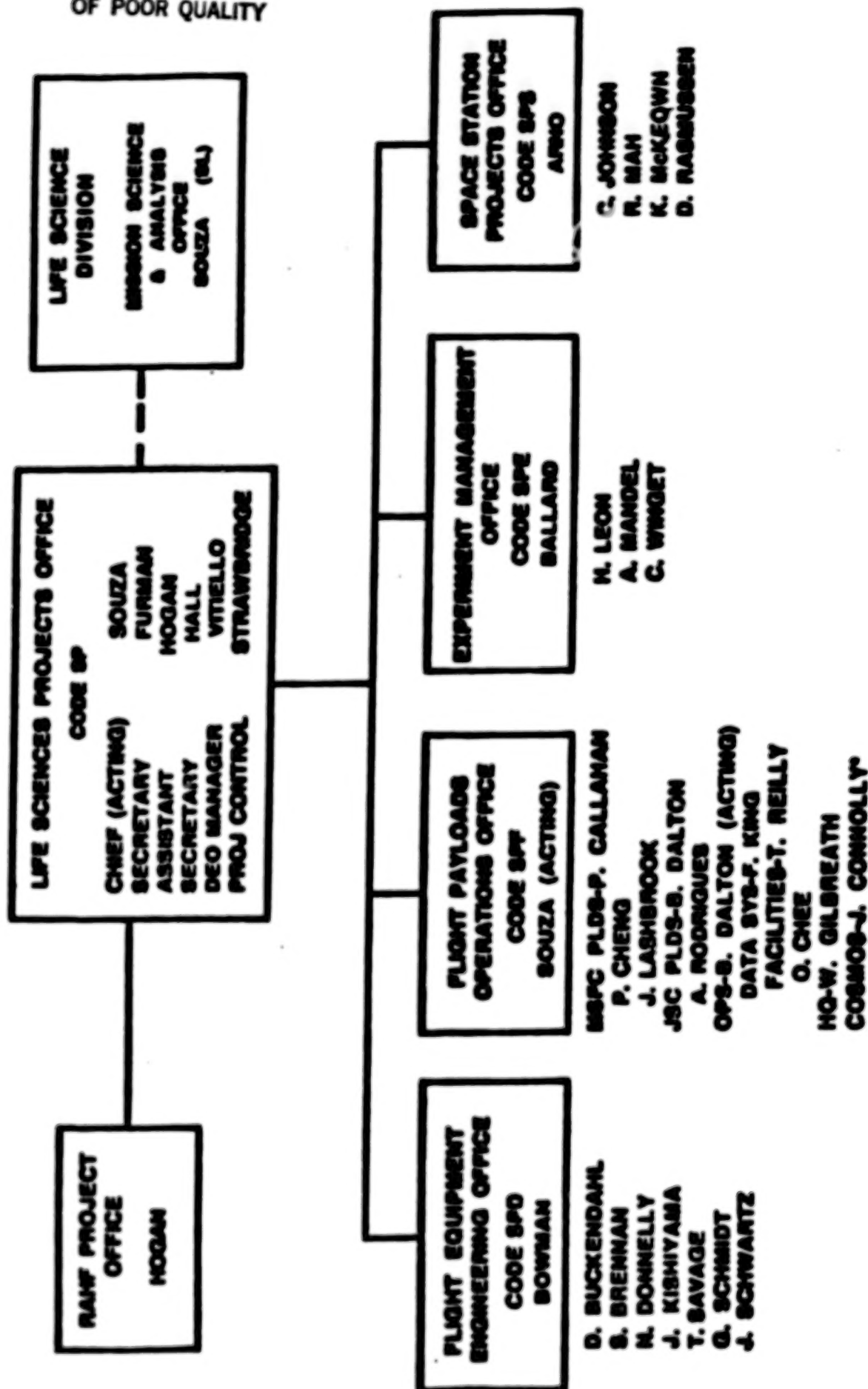
- artifacts from muscle contraction
- heavy data rate requirement from small animals

RECOMMENDATIONS:

- assess status of flexible electrodes made from metallic powder embedded in silicone rubber
- assessment of longevity of existing systems needed

ATTACHMENT 3
SCIENCE VIEWGRAPHS/HANDOUTS
ROD BALLARD

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APPROVED *LH For KAS*

DATE 6-23-87

* CODE E

REVISED 6-23-87 RPH

ATTACHMENT 3
SCIENCE VIEWGRAPHS/HANDOUTS
S. VATNER

**DESIRABLE CARDIOVASCULAR
INSTRUMENTATION
FOR SPACE FLIGHT STUDIES**

AORTIC PRESSURE

CARDIAC OUTPUT

REGIONAL BLOOD FLOW

1. RENAL

2. MESENTERIC

3. ILIAC

LV PRESSURE

LV DIMENSIONS

VENOUS PRESSURE

BLOOD PRESSURE

ARTERIAL

KONIGSBERG (invasive)
KONIGSBERG (cuff type)
OTHER

VENOUS

IN-DWELLING CATHETER

BLOOD FLOW TECHNIQUES

PULSE DOPPLER (directional)

CW DOPPLER (directional)

E. M. F.

TRANSIT-TIME

VENTRICULAR DIMENSIONS

ULTRASONIC CRYSTAL PAIRS
(transit-time)

FAST CT

PULSE-ECHO

ELECTROMAGNETIC - PROXIMITY

ATTACHMENT 3
SCIENCE VIEWGRAPHS/HANDOUTS
S. CHURCHILL

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CARDIOVASCULAR MEASUREMENTS IN THE SQUIRREL MONKEY (SAIMIRI SCIUREUS) FOR
FLIGHT EXPERIMENT 223 (FLUID AND ELECTROLYTE RESPONSE TO WEIGHTLESSNESS IN
THE SQUIRREL MONKEY)

ARTERIAL PRESSURE

METHOD: Chronic indwelling catheter

SITE: Abdominal aorta below renal artery

MATERIAL: Catheter is renothane (internal) bonded to PVC (external);
fluid filled (1:1 100 units/ml heparin:50% dextrose).

MAINTENANCE: Flushed every 2-4 days; cultured every 1-2 weeks;
routinely maintained patent and without infection up to
2 years in our laboratory.

SENSOR/TRANSDUCER: LAB: Hewlett-Packard Model 1099 transducer with
Model 8805D preamplifier; data collected on
HP chart drive either continuously or at
computer driven sample interval; data also
collected by DEC PDP1134 (MINC) computer
as systolic, diastolic and mean pressures.

FLIGHT: TBD

STABILITY: Excellent; ± 10

CALIBRATION: By mercury manometer or pressure gauge

IMPLANT TECHNIQUE: Full sterile procedure to insert catheter through
internal iliac artery into aorta; catheter is ex-
ternalized at back between shoulder blades; mesh
jacket worn at all times to protect. Position con-
firmed post-surgery by x-ray of contrast filled
catheter.

PREFLIGHT/POSTFLIGHT ACTIVITIES: In original proposal arterial pressure
would have been measured throughout a 7-10 control study three weeks
before and after flight.

ISSUES: Continuous measurement requires constant infusion (flight qual
infusion system not yet completely designed); periodic
measurement requires catheter to be flushed (crew time).

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OF POOR QUALITY

CARDIOVASCULAR MEASUREMENTS CURRENTLY MADE IN GROUND-BASED SQUIRREL MONKEY
LBPP MODEL

- ARTERIAL PRESSURE
- HEART RATE
- CENTRAL VENOUS PRESSURE

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OF POOR QUALITY

CENTRAL VENOUS PRESSURE

ALL PARAMETERS IDENTICAL TO ARTERIAL PRESSURE EXCEPT:

SITE: Catheter is inserted through external or common iliac artery into vena cava such that tip rests above diaphragm and below right heart.

STABILITY OF TRANSDUCER: LAB: Poor for long periods of time; temperature sensitive - will vary ± 2.5 mm Hg overnight (CVP - 0-2 mm Hg).

FLIGHT: TBD; stability ("zero drift") a major problem.

ATTACHMENT 3
SCIENCE VIEWGRAPHS/HANDOUTS
P. HUTCHINS

REFERENCE:

Crystal-controlled telemetry system for long-term acquisition of physiological data.

R.M. Anderson, A. Linvat and J.E. Zehr.

American Journal of Physiology 244:H162-H165, 1983.

ATTACHMENT 4

INDUSTRY VIEWGRAPHS/HANDOUTS

H. FINGER

SHUTTLE BIOINSTRUMENTATION CONSTRAINTS

"Why Can't My Lab Sensors Be Used?"

CV Instrumentation Workshop

July 21, 1987

Herb Finger - NASA ARC
Electronic Systems Branch

UNIQUE SHUTTLE REQUIREMENTS

- **Materials**
- **Longevity**
- **Reliability**

NASA Ames Research Center

HJF - 7/21/87

MATERIALS

- Shuttle is a Closed Environment
- All Materials within the Orbiter are Subject to Off-Gassing
- Flammability and Explosiveness are Further Issues
- Materials Must Withstand Extended Life

EQUIPMENT LONGEVITY

- **Implanted Sensors and Electronics Require a Minimum 9 Month Life.**
 - Post Operative Recovery Period**
 - 2 to 3 Month Pre-Flight Testing at Cape Mission (including Launch Slips)**
 - Post Flight Data Collection**
- **Drift and Calibration will Play a Significant Role in Design and Usage.**
- **Power (and related size) are Severely Constrained.**

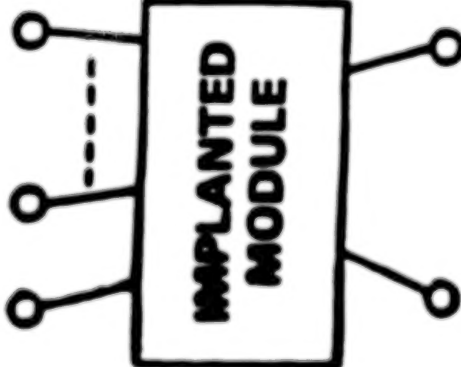
NASA RELIABILITY RQMTS

- **Component Selection (MIL-SPEC etc.)**
- **Manufacturing Standards (Soldering, PC Boards)**
- **Traceability (Configuration Control, Inspections, Travelers)**
- **Safety (AMMI or UL Electronic Std., Structural Integrity, Sharp Corners, etc.)**

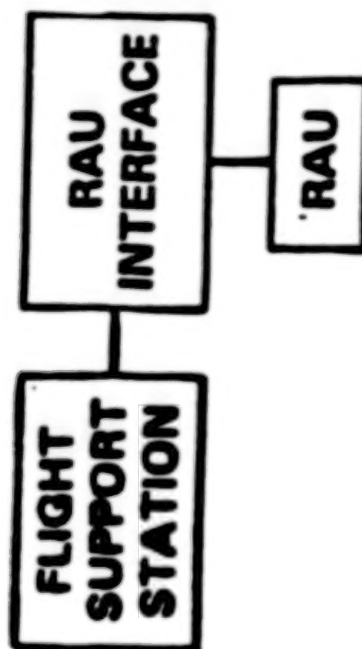
ATTACHMENT 4
INDUSTRY VIEWGRAPHS/HANDOUTS
R. EBERHARDT

PATS CONFIGURATION

TEMP EKG ?

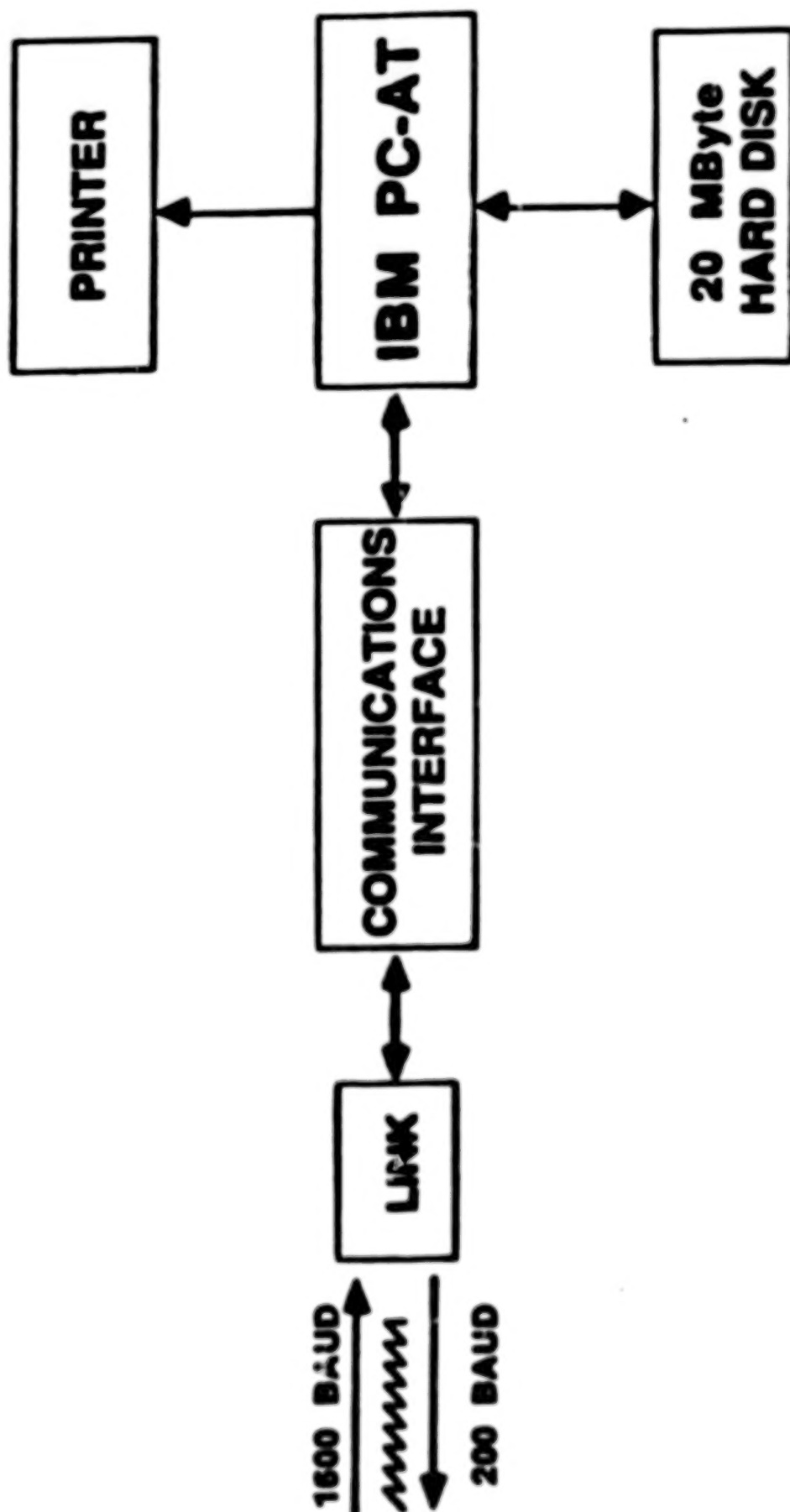


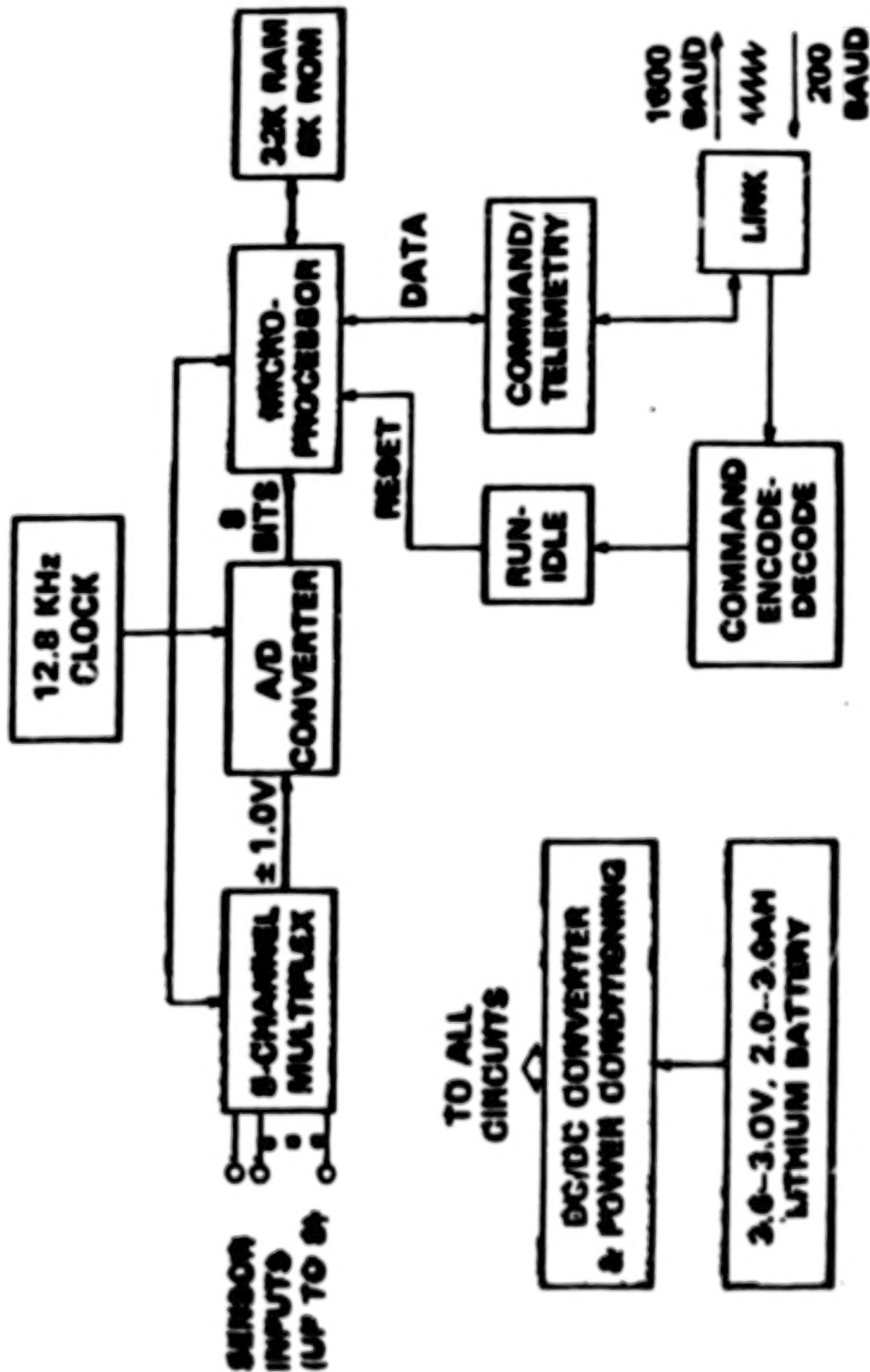
BLOOD PRESSURE
BLOOD FLOW



LINK

PAT'S CONFIGURATION (Concluded)



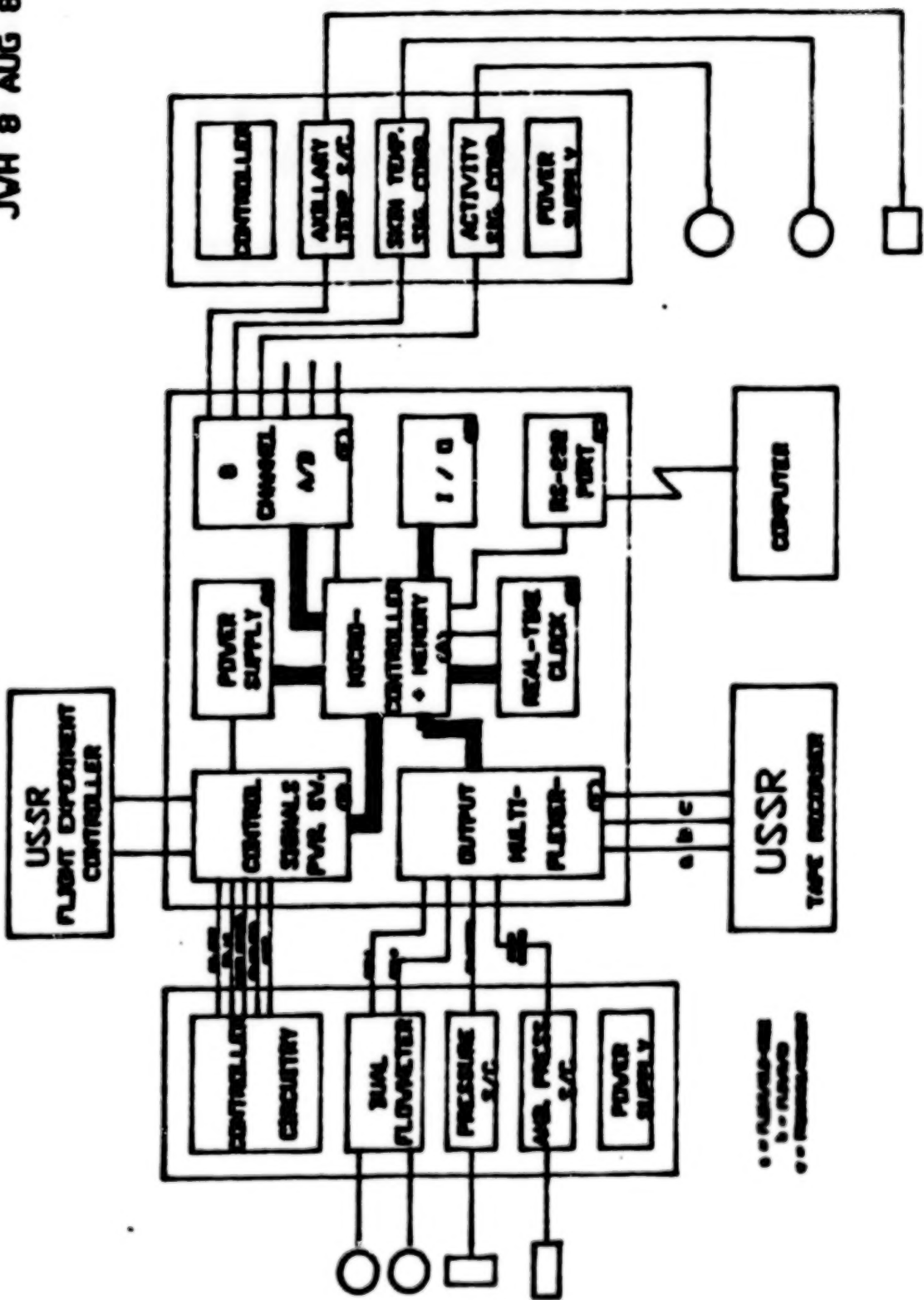


ATTACHMENT 4
INDUSTRY VIEWGRAPHS/HANDOUTS
E. LUZZI

COSMOS 1987 TIMER-CONTROLLER/DATA RECORDER (TCU/DR)

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Report Documentation Page

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15. Supplementary Notes Point of Contact: R. Ballard, Ames Research Center, MS 240-4, Moffett Field, CA 94035. (415) 694-6748 or FTS 464-6748.			
16. Abstract <p>The Ames Research Center (ARC) has a long history in the development of cardiovascular (CV) instrumentation for human and animal research. The ARC Cardiovascular Research Lab under the Space Physiology Branch, Space Research Directorate, supports both ground-based and space-based animal and human research goals. The Cardiovascular Research Laboratory was established at ARC in the mid-1960s to conduct ground-based animal research and support development of advanced cardiovascular instrumentation applicable to spaceflight. The ARC Biomedical Research Program also conducts human studies with a CV instrumentation focus.</p> <p>To evaluate the status of CV instrumentation development, a conference was conducted at ARC on July 21-22, 1987, to which NASA Primary Investigators and their engineering management were invited. A list of the 42 attendees is included in Attachment 1. A similar evaluation was conducted for ARC by a NASA contractor about 10 years ago.</p>			
17. Key Words (Suggested by Author(s)) Cardiovascular Bioinstrumentation Cardiac dimension Vascular catheters Microcirculation		18. Distribution Statement Unclassified - Unlimited Subject Category - 51	
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